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(54) **SURGICAL INSTRUMENT FOR TREATING FEMALE URINARY INCONTINENCE**

CHIRUGISCHES INSTRUMENT ZUM BEHANDELN DER WEIBLICHEN HARNINKONTINENZ

INSTRUMENT CHIRURGICAL DE TRAITEMENT DE L'INCONTINENCE URINAIRE CHEZ LA FEMME

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Description

[0001] The invention relates to a surgical instrument for treating female urinary incontinence, of the type described in WO-A-9003766, comprising a shank having a handle at one end thereof, and a curved needle-like element which is constructed to be connected with the shank to form a curved portion.

[0002] Document WO-A-9606567, which is prior art under Article 54(3)EPC, discloses a surgical incontinence device that allows for alleviating female urinary incontinence while restoring continence by attaching two curved needle to a tape that is intended to be permanently implanted into the tissue between the vaginal wall and the abdominal wall of a patient, thus strengthening the tissue required to restore the urinary incontinence. The surgical instrument according to the present application is an improvement over this instrument, where the tape comprises a netting enclosed by a thin plastic sheath such that insertion is facilitated while avoiding irritation or damage of body tissue.

[0003] The invention will be explained in more detail with reference to the accompanying drawings which disclose the surgical instrument according to the invention and wherein.

FIG. 1 is a side view of the surgical instrument according to the invention,
FIG. 2 is a plan view of the surgical instrument,
FIG. 3 is an exploded side view of one of the needles and tape and shrinkage hose to be connected with said needle,
FIG. 4 is a side view of the needle in FIG. 3 with the tape connected therewith,
FIG. 5 is an enlarged fragmentary axial cross sectional view of a coupling of the instrument for connecting an exchangeable needle thereof, and
FIG 6 is a side view of two needles and a tape interconnecting said needles.

[0004] In the following description the same reference numerals have been used as in WO-A-9606567 for corresponding details of the instrument.

[0005] The surgical instrument comprises a cylindrical tubular shank 10 having at one end thereof a handle 11. At the other end of the shank there is a socket 14. A cylindrical shaft 15 is rotatably mounted in the shank and can be rotated manually by means of a knob 16 mounted to one end of the shaft. The other end of the shaft forms a cylindrical portion 17, FIG 5, of smaller outside diameter than the shaft, which joins a portion 18 having external threads, a smooth end portion 19 of further reduced diameter joining the threaded portion 18, end portion 19 forming a guide pin at said other end of the shaft. Portions 18 and 19 are received in the portion of socket 14 projecting from the shank. The surgical instrument as described so far is in agreement with the instrument disclosed in WO-A-9606567 except that the end portion 14' of socket 14 is flattened from opposite sides (cfr FIGS 1 and 2), so that the cross section of said end portion is non-circular.

[0006] The surgical instrument also includes an exchangeable and disposable needle 21 which at one end thereof is attached to the shank at one end of the needle and extends over substantially a quarter of a circle to the other, free end thereof in order to follow substantially the profile of the pubis between the vagina and the abdominal wall. The needle has uniform circular cross section and has a smooth, preferably polished outside surface. At the free end thereof the needle forms a point 22 by being terminated by a conical portion.

[0007] For attachment of needle 21 to shank 10 the needle forms at said one end thereof a straight portion 30 which is cylindrical but has milled flat faces 31 over that part of said portion 30, extending from the adjacent end of the needle, which shall be received by socket portion 14'. The needle should be oriented in a predetermined rotational position in relation to the shank, and more particularly it should project at right angles to the plane of handle 11. This rotational position is secured by the non-circular shape of socket portion 14' and the end portion of the needle having the flat faces 31, which fits into socket portion 14'. The end portion of the needle having the flat faces 31 joins the body of the needle over e conical portion 32, which tapers towards a shoulder 33.

[0008] An axial blind hole extends from the end surface of the needle said hole having a threaded portion 23 and inwardly thereof a narrower, cylindrical portion 24. Guide pin 19 is dimensioned to be guidingly received by said latter portion when the threaded portion 18 for attaching needle 21 to the rest of the surgical instrument is screwed into threaded portion 23 of the blind hole by rotating shaft 15 by manual rotation of knob 16, the end surfaces of the shank and the needle being pressed against each other. Also this attachment is in agreement with that described in WO-A-9606567.

[0009] When the method as described in WO-A-9606567 is practised two needles 21A and 21B, FIG. 6 of the embodiment described shall be connected one at each end of a tape 26. According to the present invention the tape of the preferred embodiment comprises a mesh or netting forming openings of the order of 1 mm. A suitable material for the tape is PROLENE®, a knitted polypropylene mesh having a thickness of 0,7 mm manufactured by Ethicon, Inc., Sommerville, New Jersey, USA. This material is approved by FDA in USA for implantation into the human body. The netting (tape) preferably has a width of approximately 10 mm and is enclosed in a thin polyethylene sheath 34 which in flattened condition has substantially the same width as the tape although a difference in width is shown in FIG 2 in order to make the provision of the sheath more clear. The length of the netting should be approximately 400 mm. The netting and the sheath are interconnected by means of two rows 35 of stiching. The end portion of the

sheath is attached to the conical portion 32 of the needle by means of a suitable strong glue, and the interconnection of the needle and sheath is covered by a shrink hose 36 of rubber which extends from the shoulder 33 over the conical portion 32 and partly over the cylindrical end portion 30 of the needle. The shrink hose is substantially flush with the surface of the needle at the shoulder. By this arrangement the netting is securely attached to the needle.

[0010] The purpose of sheath 34 is above all to facilitate the insertion of the netting in the manner described in WO-A-06567 i e when the netting is pulled at the ends thereof from the vaginal wall to the abdominal skin and to avoid that rough edges of the netting irritate or damage the body tissues.

[0011] When the tape has been positioned in the correct position as a sling around the urethra the polyethylene sheath shall be removed, and in order to facilitate the removal the sheath should be perforated at the longitudinal center thereof as indicated by a dot-and-dash line 37 in FIG. 6, so that the two halves of the sheath can be withdrawn from the body by pulling at the respective outer ends thereof the halves being separated at the perforation under the influence of the pulling force.

[0012] The purpose of the polyethylene sheath is also to protect the netting during attachment to the needles and during handling before and during insertion into the body.

[0013] The longitudinal center of the tape and sheath should be indicated by a visible colour mark 38, FIG. 6 so that the surgeon readily can see when the netting is symmetrically located with reference to urethra during the surgery.

Claims

1. Surgical instrument for treating female urinary incontinence, comprising a first curved needle-like element (21A), a second curved needle-like element (21B) and a shank (10) having a handle (11) at a first end of said shank, said shank being adapted at a second end of said shank to receive the first curved needle-like element (21A) or the second curved needle-like element (21B), said elements being constructed to be connectable independently of each other with the second end of said shank and said elements being intended to be passed into the body via the vaginal wall and being dimensioned to extend from the inside surface of the vaginal wall over the back of the pubic bone to the outside of the abdominal wall, said first element being connected at one end of said first element to a first end of a tape (26), and said second element being connected at one end of said second element to a second end of said tape, said tape comprising a netting (26) enclosed by a thin plastics sheath (34).

2. Instrument as in claim 1 characterized in that the netting (26) is made of polypropylene.

3. Instrument as in claim 2 characterized in that the sheath (34) is made of polyethylene.

4. Instrument as in any of claims 1 to 3 **characterized in that** the sheath (34) is perforated at the longitudinal center thereof.

5. Instrument as in any of claims 1 to 4 **characterized in that** the netting (26) and the sheath are interconnected by stitching ((35).

6. Instrument as in any of claims 1 to 5 **characterized in that** the needle-like element (21) comprises a non-circular end portion fitting into a non-circular socket (14') at said other end of the shank (10).

7. Instrument as in claim 6 **chararacterized** in that said end portion of the needle-like element (21) joins the rest of the element by a conical portion (32) tapering towards a shoulder (33) on the needle-like element.

8. Instrument as in claim 7 characterized in that the netting (26) and the sheath (34) are connected to the needle-like element (21) by gluing to said conical portion (32).

9. Instrument as in claim 8 characterized in that the netting (26) and the sheath (34) at the site of attachement thereof are covered by a shrink hose (36).

10. Instrument as in claim 9 characterized in that one end of the shrink hose (36) abuts the shoulder (33) and is substantially flush with the surface of the needle-like element at said shoulder.

11. Instrument as in claim 9 or 11, **characterized in that** the netting (26) and the sheath (34) project from the shrink hose (36) at the other end thereof.

12. Instrument as in any of claims 1 to 11, **characterized in that** a visable marking (38) is provided on the sheath (34) at the longitudinal center thereof.

Patentansprüche

1. Chirurgisches Instrument zur Behandlung der Harninkontinenz bei Frauen, welches ein erstes gekrümmtes nadelartiges Element (21A), ein zweites gekrümmtes nadelartiges Element (21B) und einen Schaft (10) umfasst, der einen Haltegriff (11) an einem ersten Ende dieses Schafts besitzt, wobei dieser Schaft an einem zweiten Ende dieses Schafts

derart angepasst ist, dass er das erste gekrümmte nadelartige Element (21A) oder das zweite gekrümmte nadelartige Element (21B) aufnehmen kann, und diese Elemente derart konstruiert sind, dass sie unabhängig voneinander mit dem zweiten Ende dieses Schafts verbunden werden können und dazu vorgesehen sind, in den Körper über die Scheidenwand eingeführt zu werden und so dimensioniert sind, dass sie sich von der Innenseite der Scheidenwand über die Rückseite des' Schambeins bis zur Außenseite der Abdomenwand erstrecken, wobei das erste Element an einem seiner Enden mit einem ersten Ende eines Bandes (26) und das zweite Element an einem seiner Enden mit einem zweiten Ende dieses Bandes verbunden werden und dieses Band ein von einer dünnen Plastikhülle (34) umschlossenes Netzgewebe (26) umfasst.

2. Instrument nach Anspruch 1, **dadurch gekennzeichnet, dass** das Netzgewebe (26) aus Polypropylen besteht.

3. Instrument nach Anspruch 2, **dadurch gekennzeichnet, dass** die Hülle (34) aus Polyethylen besteht.

4. Instrument nach einem der Ansprüche 1 bis 3, **dadurch gekennzeichnet, dass** die Hülle (34) in ihrem Längszentrum perforiert ist.

5. Instrument nach einem der Ansprüche 1 bis 4, **dadurch gekennzeichnet, dass** das Netzgewebe (26) und die Hülle durch eine Naht (35) miteinander verbunden sind.

6. Instrument nach einem der Ansprüche 1 bis 5, **dadurch gekennzeichnet, dass** das nadelartige Element (21) ein nicht-kreisförmiges Endteil umfasst, das in eine nicht-kreisförmige Buchse (14') am anderen Ende des Schafts (10) passt.

7. Instrument nach Anspruch 6, **dadurch gekennzeichnet, dass** dieses Endteil des nadelartigen Elements (21) an das restliche Element durch ein konisches Teil (32) anstößt, das sich zu einem Anschlag (33) auf dem nadelartigen Element hin verjüngt.

8. Instrument nach Anspruch 7, **dadurch gekennzeichnet, dass** das Netzgewebe (26) und die Hülle (34) mit dem nadelartigen Element (21) verbunden sind, indem sie an diesem konischen Teil (32) ankleben.

9. Instrument nach Anspruch 8, **dadurch gekennzeichnet, dass** das Netzgewebe (26) und die Hülle (34) auf der Seite der Anheftung durch einen Schrumpfschlauch (36) bedeckt sind.

10. Instrument nach Anspruch 9, **dadurch gekennzeichnet, dass** ein Ende des Schrumpfschlauches (36) an den Anschlag (33) anstößt und im wesentlichen mit der Oberfläche des nadelartigen Elements an diesem Anschlag bündig ist.

11. Instrument nach Anspruch 9 oder 10, **dadurch gekennzeichnet, dass** das Netzgewebe (26) und die Hülle (34) vom Schrumpfschlauch (36) an dessen anderem Ende herausragen.

12. Instrument nach einem der Ansprüche 1 bis 11, **dadurch gekennzeichnet, dass** eine sichtbare Markierung (38) auf der Hülle (34) in deren Längszentrum vorgesehen ist.

Revendications

1. Instrument chirurgical pour le traitement de l'incontinence urinaire chez la femme comprenant un premier élément incurvé semblable à une aiguille (21A), un second élément incurvé semblable à une aiguille (21B) et une tige (10) ayant une poignée (11) à une première extrémité de ladite tige, ladite tige étant adaptée à une seconde extrémité de ladite tige afin de recevoir le premier élément incurvé semblable à une aiguille (21A) ou le second élément incurvé semblable à une aiguille (21B), lesdits éléments étant conçus pour pouvoir être raccordés indépendamment l'un de l'autre à la seconde extrémité de ladite tige et lesdits éléments étant prévus pour être passés dans le corps à travers la paroi vaginale et étant dimensionnés pour s'étendre de la surface intérieure de la paroi vaginale sur la partie arrière de l'os pubien jusqu'à l'extérieur de la paroi abdominale, ledit premier élément étant raccordé à une extrémité dudit premier élément à une première extrémité d'une bande (26) et ledit second élément étant raccordé à une extrémité dudit second élément à une seconde extrémité de ladite bande, ladite bande comprenant un filet (26) enfermé dans un fin fourreau en matière plastique (34).

2. Instrument selon la revendication 1, **caractérisé en ce que** le filet (26) est en polypropylène.

3. Instrument selon la revendication 2, **caractérisé en ce que** le fourreau (34) est en polyéthylène.

4. Instrument selon l'une quelconque des revendications 1 à 3, **caractérisé en ce que** le fourreau (34) présente des perforations au milieu de sa longueur.

5. Instrument selon l'une quelconque des revendications 1 à 4, **caractérisé en ce que** le filet (26) et le

fourreau (34) sont assemblés par couture (35).

6. Instrument selon l'une quelconque des revendications 1 à 5, **caractérisé en ce que** l'élément semblable à une aiguille (21) comprend une partie extrême non circulaire s'emboîtant dans une douille non circulaire (14') à ladite autre extrémité de la tige (10).

7. Instrument selon la revendication 6, **caractérisé en ce que** ladite partie extrême de l'élément semblable à une aiguille (21) se raccorde au reste de l'élément par une partie conique (32) finissant en fuseau contre un épaulement (33) de l'élément semblable à une aiguille.

8. Instrument selon la revendication 7, **caractérisé en ce que** le filet (26) et le fourreau (34) sont assemblés à l'élément semblable à une aiguille (21) par collage sur ladite partie conique (32).

9. Instrument selon la revendication 8, **caractérisé en ce que** le filet (26) et le fourreau (34) à l'endroit de leur fixation sont recouverts d'un manchon mis en place par rétraction (36).

10. Instrument selon la revendication 9, **caractérisé en ce que** l'une des extrémités du manchon (36) vient en butée contre l'épaulement (33) et arrive en grande partie au ras de la surface de l'élément semblable à une aiguille à l'endroit dudit épaulement.

11. Instrument selon la revendication 9 ou 10, **caractérisé en ce que** le filet (26) et le fourreau (34) sortent du manchon (36) à l'autre extrémité de ce dernier.

12. Instrument selon l'une quelconque des revendications 1 à 11, **caractérisé en ce qu'**un marquage visible (38) est fourni sur le fourreau (34) au milieu de la longueur de ce dernier.

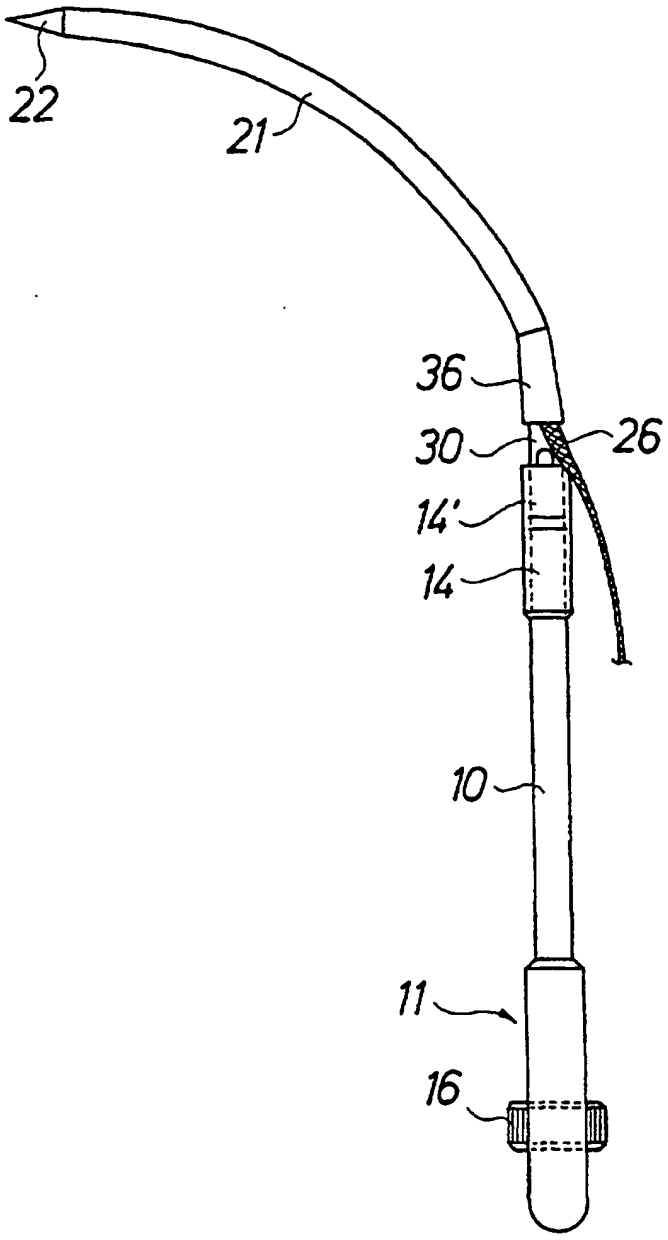

FIG. 1

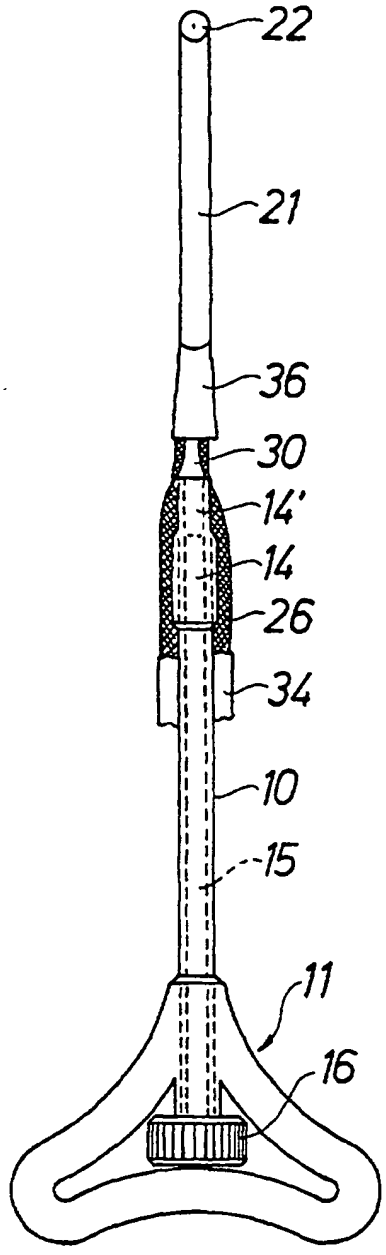

FIG. 2

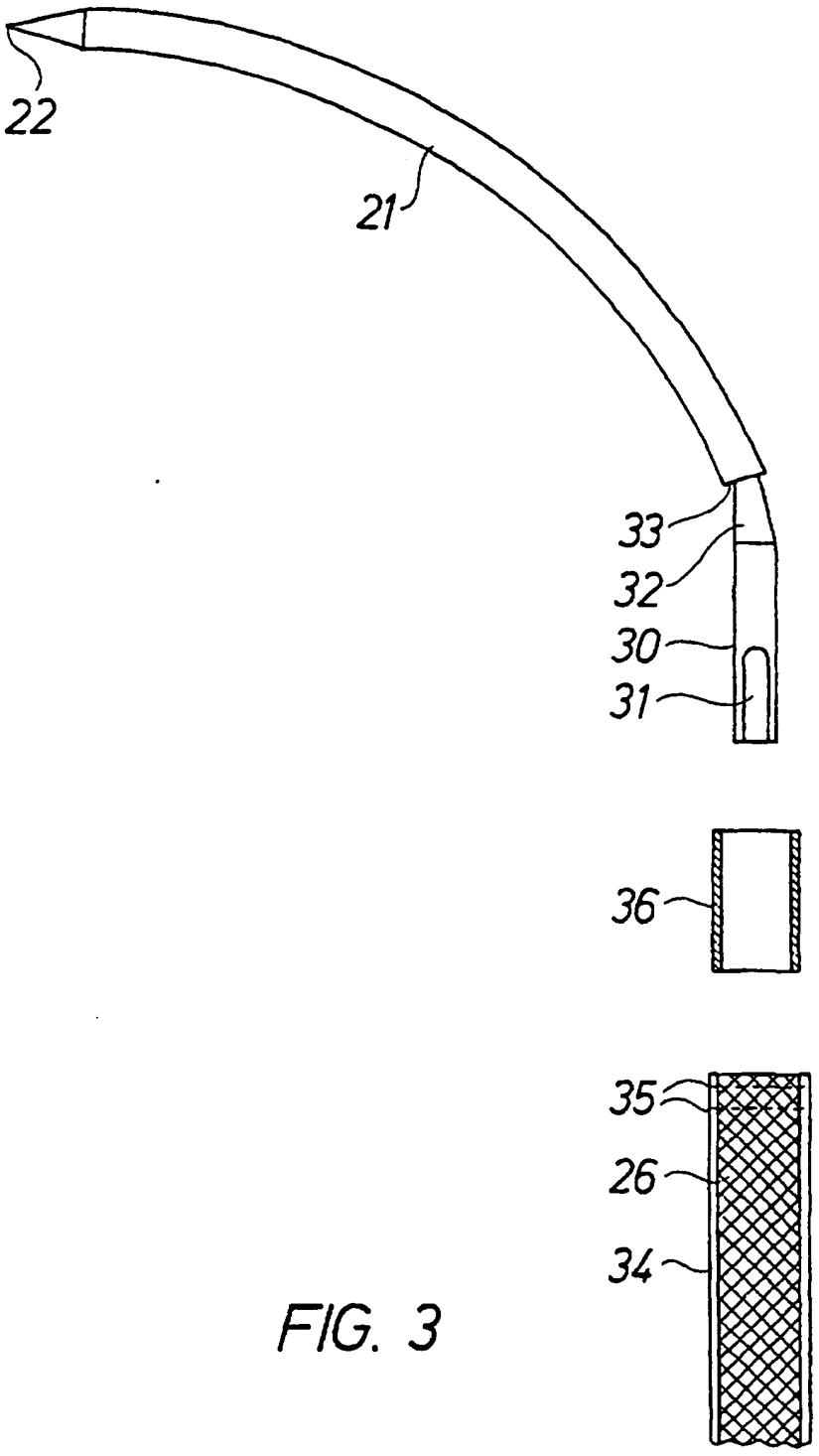

FIG. 3

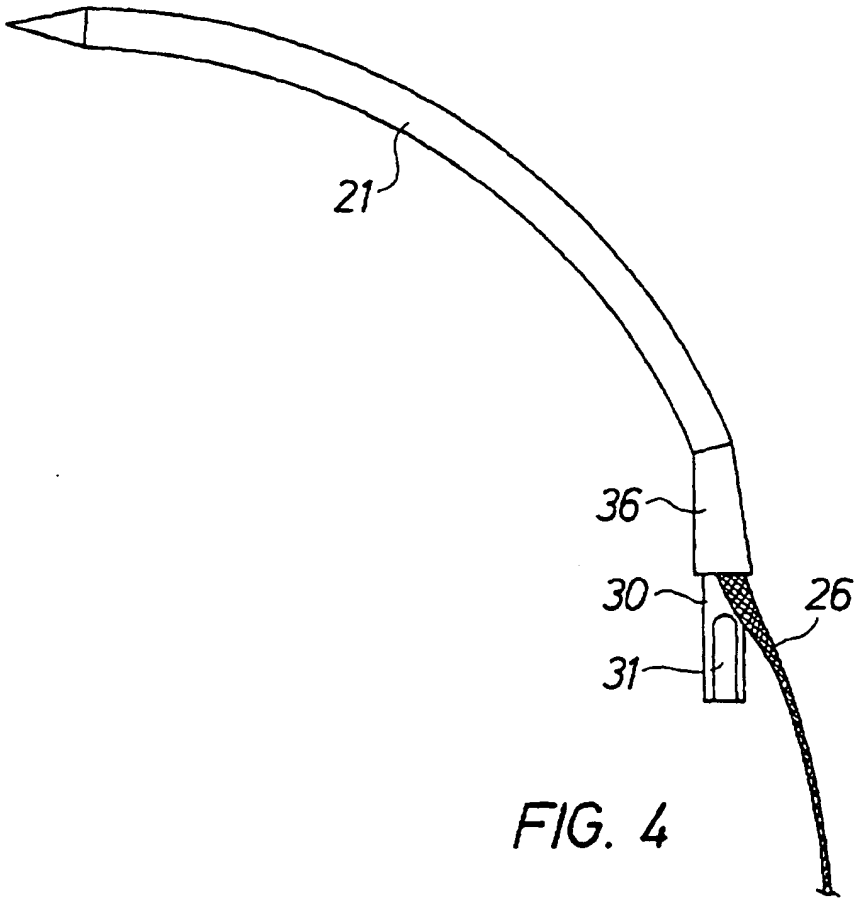

FIG. 4

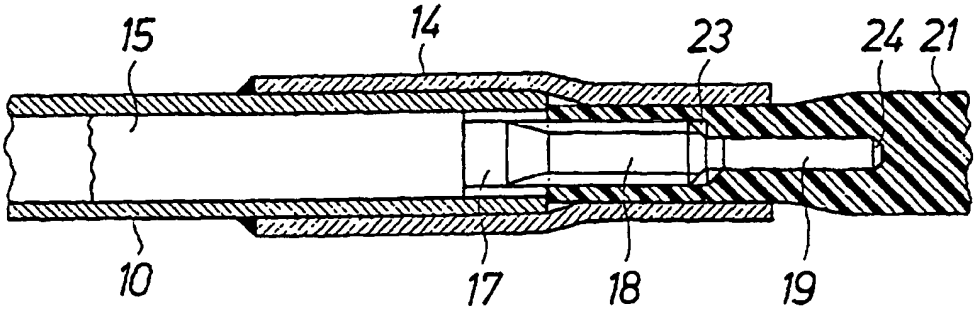

FIG. 5

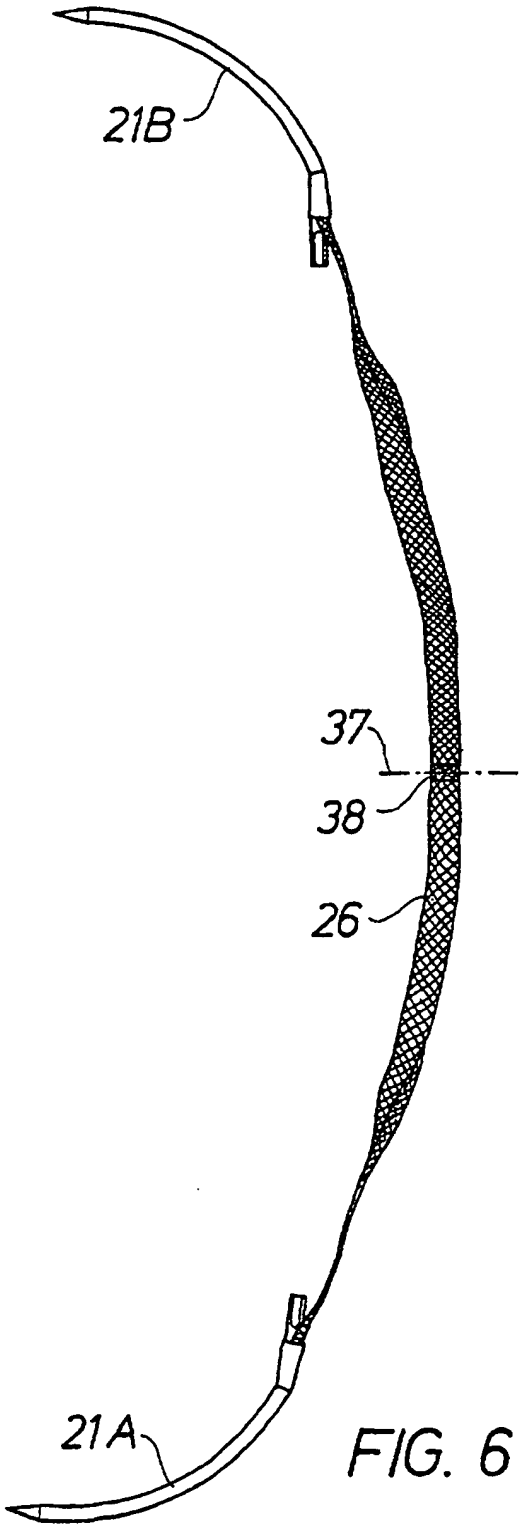

FIG. 6